REMARKS

Claims 1-21 remain before the Examiner for reconsideration. Claims1, 3, 6 and 12 have been amended.

In the Office Action dated February 26, 2004, the Examiner indicated that the information disclosure statement filed October 19, 2001 had been placed in the application file, but the information referred to therein had not been considered. Specifically, the Examiner indicates that:

> The information disclosure statement (IDS) filed 10/192001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed.
>
> It appears that the parent application (09/267,238) of the instant application did not have the following publication: 'A particulate Contrast Agent With Potential For Ultrasound Imaging Of Liver'.

Applicants respectfully assert that the IDS filed October 19, 2001 fully complied with 37 CFR 1.98(a)(2), by including copies of all required publications, including "A Particulate Contrast Agent With Potential For Ultrasound Imaging Of Liver". Applicants respectfully assert that the parent application (09/267,238) of the present divisional patent application did include the publication: "A Particulate Contrast Agent With Potential For Ultrasound Imaging Of Liver". In that regard, Applicants enclose herewith a copy of the Form PTO-A820 from the parent case including the date stamp of the United States Patent and Trademark Office and the Examiner's initials indicating that the publication had been received by the USPTO in the parent case (09/267,238) and had been considered by the Examiner. For the convenience of the Examiner, Applicants have included herewith a copy of the publication entitled "A Particulate Contrast Agent With Potential For Ultrasound Imaging Of Liver". Applicants respectfully request that the Examiner consider the publications identified in the IDS filed October19, 2001, initial a copy of the IDS Form PTO/A820 included with the IDS filed October 19, 2001 to show

consideration of the publications, and return the initialed form to the undersigned Attorney for Applicants.

The Examiner rejected claims 1, 6-8, 12, 15, 16, 20, and 21 under the judicially created doctrine of obviousness-type double patenting "as being unpatentable over claims 44 (regarding claim 1), 70 (regarding claims 6-8), 39 (regarding claims 12, 15, 16), and 25 (regarding claims 20,21) of U.S. Patent No. 6,317,623.

Specifically the Examiner asserted that:

> Although the conflicting claims are not identical, they are not patentably distinct from each other because it is obvious to an ordinary skill in the art that concentration is a property of a contrast enhancement agent. Furthermore, the claims of the instant application is broader in scope than the claims of the `623 patent.

Applicants respectfully traverse the Examiner's rejection. The present patent application is a divisional application filed as a result of a restriction requirement during the prosecution of U.S. Patent No. 6,317,623. Applicants thus respectfully assert that the Examiner's assertion of double patenting over U.S. Patent No. 6,317,623 is improper as 35 U.S.C. Section 121 sets forth that "a patent issuing on an application with respect to which a requirement for restriction under this section has been made ... shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application...."

The Examiner further rejected claim 3 under 35 U. S.C. 112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Specifically the Examiner asserted that: "Claim 3 recites the limitation "the patient" in line 2. There is insufficient antecedent basis for this limitation in the claim." Applicants have amended claim 3 to obviate the Examiner's rejection under Section 112. The amendment was inherent in the claims as filed and does not change the scope of the claim or any equivalents thereto.

The Examiner also rejected Claims 1-5 and 15-19 under 35 U.S.C. 102(b) "as being anticipated by Giddey et al. (US 5,310,540)." Specifically the Examiner asserted that:

> Giddey teaches in col. 10, lines 13-37, a method of preparing contrast agents (gas-filled microspheres) comprising the step measuring the concentration or size of the contrast agents in order to assist in properly preparing the contrast agents. Giddey further teaches the pressurizing and agitating steps (col. 9, lines 22-39). Giddey continues to teach the steps controlling the size distribution and concentration of the contrast agents (col. 9, line 36 and col. 11, line 54). Giddey's contrast agent is used for ultrasonic diagnostic imaging system which inherently suggests the step of imaging a patient.

Applicants respectfully traverse the Examiner's rejection.

Giddey discloses whipping a viscous solution of a filmogenic protein into a foam and subjecting the foam to shear to reduce the size of the foam bubbles to a range suitable for use in ultrasonic echography. Giddey, in column 9, lines 22-39, merely describes a series of experiments in which various parameters were changed between experiments and certain properties of the resultant preparation were measured and recorded. Giddey does not disclose or suggest measuring a property of the contrast enhancement agents during preparation of the medium to assist in controlling at least one parameter during preparation of the medium. Likewise, Giddey does not disclose or suggest measuring a property of the contrast enhancement agents during delivery thereof and selectively destroying one or more of the contrast enhancement agents to control the measured property.

Claims 1, 5, 15, 18, and 19 are further rejected by the Examiner under 35 U.S.C. 102(b) "as being anticipated by Cheung (US 5,194,300) or Guberek et al. (US 5,230,343) or Orsolini et al. (US 5,445,832)." Specifically the Examiner asserted that:

> Cheung teaches in col. 5, lines 4-54 or Guberek teaches in col. 5, lines 5-25 or Orsolini teaches in col. 4, lines 26-35, a method of preparing contrast agents comprising the step of measuring the size of the contrast agents."

Applicants respectfully traverse the Examiner's rejection.

Cheung discloses highly fluorescent latex microspheres and preparation thereof. The microspheres are used to visualize cell surface antigens and DNA encoding of single genes via a biotinylated DNA probe. Initially, the fluorescent markers of Cheung are not contrast enhancement agents, which are used in patient imaging. In any event, like Giddey, Cheung does not disclose or suggest measuring a property of a contrast enhancement agents during preparation of a medium to assist in controlling at least one parameter during preparation of the medium. Likewise, Cheung does not disclose or suggest measuring a property of the contrast enhancement agents during delivery thereof and selectively destroying one or more of the contrast enhancement agents to control the measured property. Chueng, at Column 5, lines 4-54, merely discloses the method of preparation of the fluorescent latex microshperes thereof and the properties of the microspheres measured after preparation.

Guberek discloses the measurement and tracing of regional myocardial blood flow and other blood flows using nonradioactive, colored microspheres. The colored microspheres of Guberek are not contrast enhancement agents used in patient imaging. Moreover, Guberek does not disclose or suggest measuring a property of a contrast enhancement agents during preparation of a medium to assist in controlling at least one parameter during preparation of the medium. Likewise, Guberek does not disclose or suggest measuring a property of the contrast enhancement agents during delivery thereof and selectively destroying one or more of the contrast enhancement agents to control the measured property. Guberek, at Column 5, lines 5-25, merely discloses the introduction of the already-prepared colored microshperes into the flow and subsequent analysis after recovery of a sample of the volume.

Orsilini et al. discloses the preparation and use of microspheres of a biodegradable polymer material incorporating a medicamentous substance for sustained and controlled release of the medicamentous substance. Orsilini et al. does not disclose or suggest a contrast enhancement agents for use in patient imaging. Furthermore, Orsilini et al. does not disclose or suggest measuring a property of a contrast enhancement agents during

preparation of a medium to assist in controlling at least one parameter during preparation of the medium. Likewise, Orsilini et al. does not disclose or suggest measuring a property of the contrast enhancement agents during delivery thereof and selectively destroying one or more of the contrast enhancement agents to control the measured property. Orsolini et al., at Column 4, lines 26-35, merely discloses that the method of preparation of that invention enables control of size of the medicamentous-substance-containing microspheres produced thereby.

Claims 6 and 10 are also rejected by the Examiner under 35 U.S.C. 103(a) "as being unpatentable over Evans, III et al. (US 5,885,216) in view of Giddey et al.". Specifically the Examiner assured that:

> Evans teaches a container (10) and a sensor adapted to measure concentration of the contrast agent but fails to mention specifically an agitation mechanism.
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> Giddey teaches in col. 9, lines 17-35, an agitation mechanism specifically used in preparation of ultrasonic contrast agents in order to agitate the contrast agents so that intended concentration of the contrast agents is achieved.
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> Therefore, it would have been obvious to an ordinary skill in the art at the time the invention was made to use the agitation mechanism of Giddey in the contrast agent preparation process of Evans so that intended concentration of the contrast agents is achieved.

Applicants respectfully traverse the Examiner's rejection.

Contrary to the Examiner's assertion, Evans does not disclose a sensor adapted to measure the concentration of a contrast medium. Evans discloses a sensor which reads a bar code on a contrast container, which can include information regarding the concentration of the contrast medium. For the reasons set forth above, the disclosure of Giddey does not overcome the deficiencies of Evans.

Finally, the Examiner objected claims 9 and 11 "as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all

of the limitations of the base claim and any intervening claims." For the reasons set forth above, Applicants respectfully assert that claims 9 and 11 are allowable as written

In view of the above amendments and remarks, the applicants respectfully requests that the Examiner withdraw the objection to the drawings and the rejections of the claims, indicate the allowability of Claims 1-21 rand arrange for an official Notice of Allowance to be issued in due course.

Respectfully submitted,

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